

Attorney Docket No.: 05432/100M919-US4



I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. 951078 in an envelope addressed to:

Mail, Airbill No. **EL 983951978** in an envelope **US**

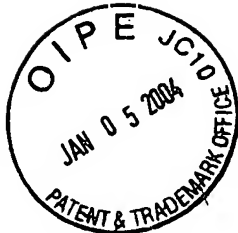
on January 5, 2004  
Date

  
Signature

D. Davis

Typed or printed name of person signing Certificate

IDS (Citation) by Applicant **W/ 41 REFERENCES**  
Preliminary Amendment (5 pages)



EXPRESS MAIL CERTIFICATE

Date \_\_\_\_\_ Label No. \_\_\_\_\_ I  
hereby certify that, on the date indicated above, this paper or fee was  
deposited with the U.S. Postal Service & that it was addressed for delivery  
to the Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-  
1450 by "Express Mail Post Office to Addressee" service.

\_\_\_\_\_  
Name (Print)

\_\_\_\_\_  
Signature

Customer No.: 07278

Docket No.: 05432/100M919-US4

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Connie Sanchez, et al.

Serial No.: 10/644,587

Art Unit: 1614

Filed: August 20, 2003

Examiner: Not Yet Assigned

For: THE USE OF ENANTIOMERIC PURE ESCITALOPRAM

-----  
**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

In order to comply with 37 CFR 1.97 and 1.98, attached hereto is a copy of form PTO/SB/08 and a copies of the documents listed thereon. The U.S. patents cited in the attached form PTO/SB/08 are not supplied pursuant to a notice of waiver of the requirement under 37 CFR 1.98(a)(2)(i) by the U.S. Patent and Trademark Office dated June 30, 2003.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each document cited be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing form PTO/SB/08 next to the document. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for

{W:\05432\100M919-US4\00110750.DOC [REDACTED] }

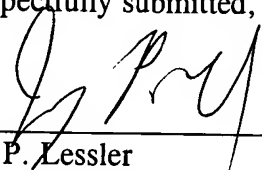
any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

The present Information Disclosure Statement is being submitted in compliance with 37 CFR 1.56, but the citation of such document is not to be construed as an admission that such document is necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner, in the normal course of examination, will make an independent search and will determine the best prior art consistent with 37 CFR 1.104(a) and in the course of each search, will review for relevance every document cited on the attached form even if not initialed.

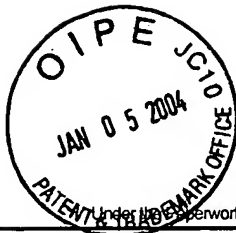
This submission is filed before the mailing date of a first Office action on the merits. It is believed that no fee is due. However, if the Commissioner determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 04-0100 for any deficiency up to \$2500.00.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

  
\_\_\_\_\_  
Jay P. Lessler  
Registration No. 41,151  
Attorney for Applicant(s)

DARBY & DARBY  
Post Office Box 5257  
New York, NY 10150-5257  
(212) 527-7700



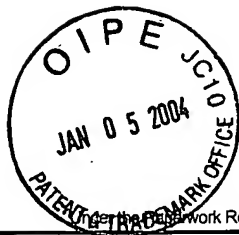
PTO/SB/08a/b (08-03)  
Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

|  |   |    |   |                          |                   |
|--|---|----|---|--------------------------|-------------------|
| Substitute for form 1449A/B/PTO  |   |    |   | <b>Complete if Known</b> |                   |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br><i>(Use as many sheets as necessary)</i> |   |    |   | Application Number       | 10/644,587        |
|  |   |    |   | Filing Date              | August 20, 2003   |
|  |   |    |   | First Named Inventor     | Connie Sanchez    |
|  |   |    |   | Art Unit                 | N/A               |
|  |   |    |   | Examiner Name            | Not Yet Assigned  |
| Sheet  | 1 | of | 3 | Attorney Docket Number   | 05432/100M919-US4 |

| U.S. PATENT DOCUMENTS |                       |  |                                |  |   |
|-----------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials*    | Cite No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|                       |                       | Number-Kind Code <sup>2</sup> (if known) |                                |  |   |
|                       | 1.                    | US-6,469,064 B2                          | 10-22-2002                     | Druzgala   |   |
|                       | 2.                    | US-6,333,357 B1                          | 12-25-2001                     | Eig  |   |
|                       | 3.                    | US-6,159,971                             | 12-12-2000                     | Berg et al.  |   |
|                       | 4.                    | US-6,147,072                             | 11-14-2000                     | Bymaster et al.                                    |   |
|                       | 5.                    | US-6,069,177                             | 05-30-2000                     | Carlier et al.                                     |   |
|                       | 6.                    | US-5,962,514                             | 10-05-1999                     | Evenden et al.                                     |   |
|                       | 7.                    | US-5,958,429                             | 09-28-1999                     | Wong   |   |
|                       | 8.                    | US-5,788,986                             | 08-04-1998                     | Dodman   |   |
|                       | 9.                    | US-5,648,396                             | 07-15-1997                     | Young et al.                                       |   |
|                       | 10.                   | US-5,296,507                             | 03-22-1994                     | Tanaka et al.                                      |   |
|                       | 11.                   | US-5,114,976                             | 05-19-1992                     | Norden   |   |
|                       | 12.                   | US-4,962,128                             | 10-09-1990                     | Doogen et al.                                      |   |
|                       | 13.                   | US-4,943,590                             | 07-24-1990                     | Boegesoe et al.                                    |   |
|                       | 14.                   | US-4,902,710                             | 02-20-1990                     | Foster et al.                                      |   |
|                       | 15.                   | US-4,650,884                             | 01-23-1979                     | Bogeso et al.                                      |   |
|                       | 16.                   | US-4,136,193                             | 01-23-1979                     | Bogeso et al.                                      |   |
|                       | 17.                   | US-3,467,675                             | 09-16-1969                     | Peterson et al.                                    |   |
|                       | 18.                   | US-Re. 34712                             | 08-30-1994                     | Boegesoe et al.                                    |   |

| FOREIGN PATENT DOCUMENTS |                       |   |                                |  |   |                |
|--------------------------|-----------------------|---|--------------------------------|--|---|----------------|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where Relevant<br>Passages or Relevant<br>Figures Appear | T <sup>6</sup> |
|                          |                       | Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known) |                                |  |   |                |
|                          | 19.                   | EP-0 347 066 A1   | 12-20-1989                     | H. Lundbeck A/S                                    |   |                |
|                          | 20.                   | WO-01/03694 A1  | 01-18-2001                     | H. Lundbeck A/S                                    |   |                |
|                          | 21.                   | WO-00/15220   | 03-23-2000                     | Astra Aktiebolag                                   |   |                |
|                          | 22.                   | WO-01/54681 A2  | 08-02-2001                     | Massachusetts Institute of Technology              |   |                |
|                          | 23.                   | WO-00/15219   | 03-23-2000                     | Astra Aktiebolag                                   |   |                |
|                          | 24.                   | WO-00/03701   | 01-27-2000                     | Massachusetts Institute of Technology              |   |                |
|                          | 25.                   | WO-00/02551   | 01-20-2000                     | NPS Pharmaceutical, Inc.                           |   |                |
|                          | 26.                   | EP-0759299  | 02-26-1997                     | Eli Lilly and Company                              |   |                |
|                          | 27.                   | EP-0714663 A2   | 06-05-1996                     | Eli Lilly and Company                              |   |                |
|                          | 28.                   | WO-93/09769   | 05-27-1993                     | Sepracor, Inc.                                     |   |                |
|                          | 29.                   | WO-92/18005   | 10-29-1992                     | National Institutes of Health                      |   |                |
|                          | 30.                   | WO-00/34263   | 06-15-2000                     | H. Lundbeck A/S                                    |   |                |
|                          | 31.                   | EP-0474580  | 03-11-1992                     | H. Lundbeck A/S                                    |   |                |

|                |  |                 |  |
|----------------|--|-----------------|--|
| W:054<br>32100 |  | Date Considered |  |
|----------------|--|-----------------|--|



PTO/SB/08a/b (08-03)  
Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

|   |   |    |   |                          |                   |
|---|---|----|---|--------------------------|-------------------|
| Substitute for form 1449A/B/PTO   |   |    |   | <b>Complete if Known</b> |                   |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   |    |   | Application Number       | 10/644,587        |
|   |   |    |   | Filing Date              | August 20, 2003   |
|   |   |    |   | First Named Inventor     | Connie Sanchez    |
|   |   |    |   | Art Unit                 | N/A               |
|   |   |    |   | Examiner Name            | Not Yet Assigned  |
| Sheet   | 2 | of | 3 | Attorney Docket Number   | 05432/100M919-US4 |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS |                       |   |                |  |
|---------------------------------|-----------------------|---|----------------|--|
| Examiner Initials <sup>1</sup>  | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |  |
|                                 | 32.                   | Kornstein, S.C. and Schneider, R.K., Clinical features of treatment-resistant depression, J. Clin. Psychiatr 2001, 62 Suppl 16, 18-25   |                |  |
|                                 | 33.                   | Nierenberg, A.A and DeCecco, L.M., Definitions of antidepressant treatment response, remission, non-response, partial response, and other relevant outcomes: A focus on treatment-resistant depression, J. Clin. Psychiatr 2001, 62 Suppl 16, 5-9               |                |  |
|                                 | 34.                   | Sackeim, H.A., The definition and meaning of treatment-resistant depression, J. Clin. Psychiatr 2001, 62 Suppl 16, 10-17  |                |  |
|                                 | 35.                   | Willner, P., Psychopharmacology, 1997, 134, 319-329   |                |  |
|                                 | 36.                   | A.F. Joubert et al., "Citalopram and Anxiety Disorders," Rev. Contemp. Pharmacother 10: 79-131 (1999)   |                |  |
|                                 | 37.                   | Ulla M. Lepola et al., "A Controlled Perspective, 1-Year Trial of Citalopram in the Treatment of Panic Disorder," J. Clin. Psychiatry 59, 10: 528-534 (1998)  |                |  |
|                                 | 38.                   | H. Koponen et al., "Citalopram in the treatment of obsessive-compulsive disorder: an open pilot study," Acta Psychiatrica Scandinavica 96:343-346 (1997)  |                |  |
|                                 | 39.                   | Dan J. Stein et al., "Use of serotonin selective reuptake inhibitor citalopram in obsessive-compulsive disorder," Journal of Serotonin Research 1: 29-33 (1996)   |                |  |
|                                 | 40.                   | Bigler, Allan et al., "Quantitative Structure-activity Relationships in a Series of Selective 5-HT uptake inhibitors," Eur. J. Med. Chem. 3:289-295 (1997)  |                |  |
|                                 | 41.                   | Soraya Seedat et al., "Open Trial of Citalopram in adults with post-traumatic stress disorder," International Journal of Neuropsychopharmacology 3: 135-140 (2000)  |                |  |
|                                 | 42.                   | Ihoko Muraki et al., "Effect of subchronic lithium carbonate treatment on anxiolytic-like effect of citalopram and MKC-242 in conditioned fear stress in the rat," European Journal of Pharmacology 383:223-229 (1999)  |                |  |
|                                 | 43.                   | Jennifer Y. Tan et al., "Citalopram in the Treatment of Depression and Other Potential Uses in Psychiatry," Pharmacotherapy 19, 6: 675-689 (1999)   |                |  |
|                                 | 44.                   | Mario Amore et al., "Short-term and Long-term evaluation of Selective Serotonin Reuptake Inhibitors in the Treatment of Panic Disorder: Fluoxetine vs. Citalopram," Hum. Psychopharmacol. Clin. Exp. 14: 435-440 (1999)   |                |  |
|                                 | 45.                   | Emanuela Mundo, M.D. et al., "Efficacy of Fluvoxamine, Paroxetine, and Citalopram in the Treatment of Obsessive-Compulsive Disorder: A Single-Blind Study," Journal of Clinical Psychopharmacology 17, 4: 267-271 (August 1997)                                 |                |  |
|                                 | 46.                   | Zoltan Rihmer, "Successful treatment of salbutamol-induced panic disorder with citalopram," European Neuropsychopharmacology 7:241-242 (1997)   |                |  |
|                                 | 47.                   | Takeshi Inoue et al., "Effect of citalopram, a selective serotonin reuptake inhibitor, on the acquisition of conditioned freezing," European Journal of Pharmacology 311: 1-6 (1996)  |                |  |

|                  |                 |  |
|------------------|-----------------|--|
| {W:054<br>32/100 | Date Considered |  |
|------------------|-----------------|--|



PTO/SB/08a/b (08-03)  
Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

|  |   |    |   |                          |                   |
|--|---|----|---|--------------------------|-------------------|
| Substitute for form 1449A/B/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   |    |   | <b>Complete if Known</b> |                   |
|  |   |    |   | Application Number       | 10/644,587        |
|  |   |    |   | Filing Date              | August 20, 2003   |
|  |   |    |   | First Named Inventor     | Connie Sanchez    |
|  |   |    |   | Art Unit                 | N/A               |
|  |   |    |   | Examiner Name            | Not Yet Assigned  |
| Sheet  | 3 | of | 3 | Attorney Docket Number   | 05432/100M919-US4 |

|     |   |  |
|-----|---|--|
| 48. | U. Lepola et al., "Citalopram in the Treatment of Early-onset Panic Disorder and School Phobia," Pharmacopsychiatry 29: 30-32 (January 1996)  |  |
| 49. | J. Hyttel et al., "The Pharmacology of Citalopram," Rev. Contemp. Pharmacother. 6: 271-285 (1995)   |  |
| 50. | American Psychiatric Associations, "DSM-IV" (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition): 393-444 (1994)   |  |
| 51. | Hytell, J., Prog. Neuro-Psychopharmacol. & Biol. Psychiat., 1982, 6, 277-295  |  |
| 52. | Gravem, A., Acta Psychiatr. Scand., 1987, 75, 478-486   |  |
| 53. | Sanchez, C., Effect of serotonergic drugs on footshock-induced ultrasonic vocalization in adult male rats, Behav. Pharmacol. 1993; 4:267-277  |  |
| 54. | Sanchez, C., Pharmacol. Toxicol. 77, 71-78 (1995)   |  |
| 55. | Sanchez, C., R-citalopram attenuates anxiolytic effects of escitalopram in a rat ultrasonic vocalisation model, European Journal of Pharmacology, 464, 2003, pp.155-158                             |  |
| 56. | Montgomery, S. et al., Escitalopram (S-Enantiomer of Citalopram): Clinical Efficacy and Onset of Action Predicted from a Rat Model, Pharmacology & Toxicology, 2001, 88, 282-286                    |  |
| 57. | Sanchez, C., Stress-induced vocalisation in adult animals: A valid model of anxiety?, European Journal of Pharmacology, 463 (2003) 133-143  |  |
| 58. | Burke, W., et al., Fixed-Dose Trial of the Single Isomer SSRI Escitalopram in Depressed Outpatients, J. Clin Psychiatry, 63:4, April 2002   |  |
| 59. | Wade, A., et al., Escitalopram 10 mg/day is effective and well tolerated in a placebo-controlled study in depression in primary care, International Clinical Psychopharmacology 2002, Vol. 17 No. 3 |  |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

|                  |  |                    |  |
|------------------|--|--------------------|--|
| {W:054<br>321100 |  | Date<br>Considered |  |
|------------------|--|--------------------|--|